GOVERNMENT OF ANDHRA PRADESH
ABSTRACT

HM & FW Department - Drug Control Administration – Include an officer from the Drugs Control Department in the inspection or enquiry teams for periodical monitoring of the quality of the In-Vitro Diagnostic kits and Reagents that are being used in the Diagnostic laboratories - Orders – Issued.

HEALTH, MEDICAL & FAMILY WELFARE (I.1) DEPARTMENT

G.O.Rt.No.625 **Dated:14.08.2023**

Read the following;

1. G.O.Ms.No.123, HM & FW (I.1) Dept., dated.05.10.2020.
2. From the DG DCA, A.P., Vijayawada, Lr Rc.No.2136175/M2-II/2023, dt.12.07.2023.

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ORDER:

The Director General, Drug Control Administration, A.P., Vijayawada in the reference 2nd read above has stated that the import, manufacturing, sale and distribution of in-vitro Diagnostic Medical Devices are regulated as Drugs under sub-clause (i) of clause (b) of section 3 and sub-clause (iv) of clause (b) of section 3 of Drugs and Cosmetics Act, 1940. The Laboratory investigations are essential for medical diagnosis in patient care and quality of diagnostic kits and reagents play important role in obtaining accurate results. The Diagnostics Laboratories in Andhra Pradesh are licensed and controlled under the "Andhra Pradesh Allopathic Private Medical Care Establishments (Registration and Regulation) Act, 2002" and "Andhra Pradesh Allopathic Private Medical Care Establishments (Registration and Regulation) Rules, 2007". Diagnostics Laboratories procure the in-vitro Diagnostic Kits and Reagents for the Laboratory Investigations and the same should be manufactured by the licensed manufacturers and purchased from the licensed dealers, alone.

2. He has further stated that as per Sec.8 of the "Andhra Pradesh Allopathic Private Medical Care Establishments (Registration and Regulation) Act, 2002", the authority (D.M.H.O at District level) may cause an inspection or enquiry in respect of any private medical care establishment, Laboratories, by deputing the any team of at least two Officers.

3. The Director General, Drug Control Administration, A.P., Vijayawada has requested the Government to include an officer from the Drugs Control Department in the above-said teams for approval and periodical monitoring of the quality of the In-Vitro Diagnostic kits and Reagents that are being used in the Diagnostic laboratories.

4. Government after careful examination of the matter hereby directed to all the DM & HOs to include an officer from the Drugs Control Department in the inspection or enquiry teams for approval and periodical monitoring of the quality of the In-Vitro Diagnostic kits and Reagents that are being used in the Diagnostic laboratories.

(PTO)

5. The Director General, Drug Control Administration, A.P., Vijayawada/ Director of Public Health & Family Welfare, A.P., Vijayawada/All DM&HOs shall take further action in the matter.

(BY ORDER AND IN THE NAME OF THE GOVERNOR OF ANDHRA PRADESH)

M.T.KRISHNA BABU
SPECIAL CHIEF SECRETARY TO GOVERNMENT

To
The Director General, Drug Control Administration, A.P., Vijayawada
The Director of Public Health & Family Welfare, A.P., Vijayawada.
The All DM&HOs in the State of A.P.
Copy to:
The PS to Spl Chief Secretary to Government, HM & FW Department.
The PA to Secretary to Government, HM & FW Department.
SF/SCs.

// FORWARDED :: BY ORDER //

SECTION OFFICER